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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,558	02/27/2004	Brendan M. Donohoe	151	9249

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/789,558	<b>Applicant(s)</b> DONOHOE ET AL.	
	<b>Examiner</b> Diane Yabut	<b>Art Unit</b> 3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/27/04; 4/29/05; 8/16/05</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS: 10/26/05; 5/12/06</u> .           |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 27 February 2004, 29 April 2005, 16 August 2005, 26 October 2005, and 12 May 2006 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### ***Claim Objections***

2. Claim 14 is objected to because of the following informalities: On line 1 of Claim 14 it reads "wherein the device is deliver and deploy" and should be changed to --wherein the device delivers and deploys--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

Art Unit: 3734

directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 3, 4, 6-9, 12-17, and 19-20 are rejected under 35 U.S.C. 102(e) as being anticipated by **Nobis et al.** (U.S. Patent No. **6,605,098**).

Claims 3, 9, 12, and 16: Nobis et al. discloses a tool body **102** having a lumen and an aperture at a distal end thereof, a cutting device **600** configured to form the opening in the target vessel ("first vessel" or "first hollow organ"), the cutting device being movable at least partially within the lumen and having a distal end configured to form the opening in the target vessel, at least the distal end of the cutting device movable through the aperture, and a graft vessel attachment device **200** movable at least partially within the lumen for delivering the implantable anastomosis device to the target vessel to connect the graft vessel ("second vessel" or "second hollow organ") to the target vessel, and having a distal end configured to connect the graft vessel to the target vessel, at least the distal end of the graft vessel attachment device movable through the aperture, wherein the cutting device is movable along a first path, or direction, and the graft vessel attachment device is movable along a second path, or direction, which is non-parallel to the first path, or away from the axial centerline of the lumen (Figures 1, 10, 12, 15a and col. 6, lines 42-67, col. 8, lines 1-14 and 34-62).

Claim 4: Nobis et al. discloses a cutting device **600** includes a substantially circular cutting element, in that it has a diameter (Figure 6).

Art Unit: 3734

Claim 6: Nobis et al. discloses both the graft vessel attachment device and the cutting device are contained within the tool body simultaneously (Figure 12).

Claim 7: Nobis et al. discloses an introducer **110** connected to the tool body, the introducer having a lumen substantially coaxial with the lumen of the tool body (Figure 1).

Claims 8, 15, 17, 19, and 20: Nobis et al. discloses the tool body including an off-axis area defined therein, and wherein at least one member of the group, consisting of the graft vessel attachment device and the cutting device, is configured to move away from the axial centerline of the lumen into the off-axis area, or a second path, and discloses the graft vessel attachment device being movable substantially along the first direction, or first path axial along the centerline of the lumen, wherein the first path and the second path form a Y-shape and intersect (col. 8, lines 1-14).

Claim 13: Nobis et al. discloses the device being configured to form the opening without passing the cutting device or the graft vessel attachment device through a lumen of the graft vessel (Figure 12 and col. 9, lines 13-51).

Claim 14: Nobis et al. discloses the device delivering and deploying the implantable anastomosis device without passing the cutting device or the graft vessel attachment device through a lumen of the graft vessel (col. 7, lines 25-37 and col. 10, lines 46-60).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3734

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 10, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobis et al.** (U.S. Patent No. **6,605,098**) in view of **Vargas et al.** (U.S. Patent No. **6,673,088**).

Claims 1, 10, and 18: Nobis et al. discloses the claimed device, including a tool body including an introducer configured to substantially seal against the target vessel, a cutting device movably attached to the tool body and configured to form the opening in the target vessel, and a graft vessel attachment device movably attached to the tool body and configured to connect the graft vessel to the target vessel and movable along a first and second path (see paragraph 5 above), except for the cutting device also being movable substantially along a first direction and transverse to the first direction, or a second path or direction.

Vargas et al. teaches a tissue punch for creating a hole in the wall of a target blood vessel wherein the cutting device is movable along a first direction along the axis of the tissue punch tool body and also transverse to the first direction, or along a second path or direction (Figures 1-5). Vargas et al. teaches that the cutting element moves in first and second directions in order to punch a hole in the target vessel and then to allow the anastomosis device to be deployed through the lumen of the tool body (col. 4, lines 63-67). It would have obvious to one of ordinary skill in the art at the time of invention to provide a cutting device movable along first and second directions, as taught by Vargas

Art Unit: 3734

et al., to Nobis et al. in order to make way for another device, such as an anastomosis device, to be deployed through the tool body.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobis et al.** (U.S. Patent No. **6,605,098**) and **Vargas et al.** (U.S. Patent No. **6,673,088**) as applied to Claim 1 above, and further in view of **Killion et al.** (U.S. Patent No. **5,921,957**).

Claim 2: Nobis et al. and Vargas et al. disclose the claimed device except for the introducer being splittable.

Teaches an introducer ("tip") being splittable in order to accommodate wider diameter instruments to be inserted through the introducer (col. 5, lines 4-15). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a splittable introducer, as taught by Killion et al., to Nobis et al. and Vargas et al. in order to accommodate larger instruments to be inserted through the introducer.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over by **Nobis et al.** (U.S. Patent No. **6,605,098**) in view of **Sirimanne et al.** (U.S. Patent No. **6,136,014**).

Claim 5: Nobis et al. discloses the claimed device except for the cutting device including an auger.

Sirimanne et al. teaches a cutting device **168** including an auger **166** that is helpful in separating the excised tissue from the cutting surface and the remaining tissue and maintains the integrity and continuity of the removed tissue (Figure 4A and col. 7, lines 27-40). It would have been obvious to one of ordinary skill in the art at the

Art Unit: 3734

time of invention to provide an auger, as taught by Sirimanne et al., to Nobis et al. in order to efficiently separate excised tissue from remaining tissue from the cutting surface.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER